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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,347	10/12/2001	Anabella Villalobos	PC10803A	1717
23913	7590	03/10/2004	EXAMINER	
PFIZER INC 150 EAST 42ND STREET 5TH FLOOR - STOP 49 NEW YORK, NY 10017-5612			KIM, JENNIFER M	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/976,347	Applicant(s) VILLALOBOS ET AL.	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 12-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on November 20, 2003 have been received and entered into the application.

The objection to the specification set forth in last Office Action is withdrawn in view of Applicants' amendment.

The rejection of claims 9-11 of record under 35 U.S.C. 112 second paragraph is hereby expressly withdrawn in view of Applicants' amendment.

The rejection of claims 1-11 of record under 35 U.S.C. 103 (c) over Applicants' admission is hereby expressly withdrawn in view of Applicant's amendment.

Claims 1-11 of record rejected under 35 U.S.C. 103 (a) over Albaugh et al. (U.S. Patent No. 6,143,760) in view of Bruns et al. (1999) is maintained for the reasons stated in the previous office action.

Response to Arguments

Applicants' arguments filed November 20, 2003 have been fully considered but they are not persuasive. Applicants argue that neither of the references (Albough et al., Burns et al.) teach or suggest the combination of a GABA receptor antagonist with an acetylcholinesterase inhibitor and the present inventors have quantitatively claimed GABA inverse agonist within unexpected functional potency and efficacy limits. This is not persuasive because Albaugh et al. teach Applicants' GABA_A cognitive enhancer set

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forth in claims 1-11 useful for the treatment of cognitive disorders. (abstract, columns 2-3, column 48, claim 38). Burns et al. teach acetylcholinesterase inhibitor, donepezil useful for treating cognitive disorder. Therefore it would have been *prima facie* obvious to combine the GABA_A inverse agonists and acetylcholinesterase inhibitors conjointly in a formulation to treat cognitive disorders. The motivation for combining the components flows from their individually known common utility (see *In re Kerkhoven*, 205 USPQ 1069(CCPA 1980)). With regard to claimed GABA inverse agonist having potency and efficacy limits of a previously known active agent taught by the prior art can not impart patentability to claims to the known active agent because such potency and efficacy limits is expected from combining the very same GABA inverse agonist with the same effective (overlapping) amounts (from about 0.1mg to about 140 mg per kg per day, column 29, lines 58-62, Albough et al.) and the very same acetylcholinesterase and same effective (overlapping) amounts (5 g or 10 mg donepezil per day; equivalent to 0.0714mg/kg to 0.142mg/kg per 70kg weight patient) as modified by the references would have same potency and efficacy as claimed by the Applicants' without surprising and unexpected result.

In view of the above Office Action of October 23, 2003 is deemed proper and asserted with full force and effect herein to obviate applicants' claims.

Claim Rejections - 35 USC § 103

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Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albaugh et al. (U.S. Patent No. 6,143,760) in view of Bruns et al. (1999).

Albaugh et al. teach Applicants' GABA_A inverse agonists set forth in claims 1-11 useful for treating cognitive disorders. (abstract, columns 2-3, column 48, claim 38).

Albaugh et al. do not teach the combination of the GABA_A inverse agonists and acetylcholinesterase inhibitors in a pharmaceutical composition and the functional efficacy set forth in claims 1-5.

Burns et al. teach acetylcholinesterase inhibitor, donepezil useful for treating cognitive disorder.

It would have been obvious to one of ordinary skill in the art to employ combinations of the GABA_A inverse agonists and acetylcholinesterase inhibitors in a pharmaceutical composition to treat cognitive disorders because all the components are well known individually for treating cognitive disorders. It would be expected that the combination of components would treat cognitive disorders as well. The motivation for combining the components flows from their individually known common utility (see *In re Kerkhoven*, 205 USPQ 1069 (CCPPA 1980)). It would have been prima facie obvious to combine the GABA_A inverse agonists and acetylcholinesterase inhibitors conjointly in a formulation to treat cognitive disorders. The functional efficacy set forth in claims 1-5 is obvious property of the same GABA_A inverse agonists to be utilized in above modified pharmaceutical composition.

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For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

jmk
February 25, 2004